

# IAP3 Rec'd PCT/PTO 15 DEC 2005

# NATED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Mogens FENGER Serial No. 10/527,806

IA Filing Date: September 12, 2003 For: METHOD OF RAPID DETECTION OF MUTATION AND

Atty's Dkt: FENGER2 Application Division ATTN: PCT Washington, D.C. Confirmation No. 3041 Date: December 15, 2005

#### LATE SUBMISSION OF DECLARATION AND/OR LATE FEES IN APPLICATION FILED UNDER 35 USC 371

U.S. Patent and Trademark Office **Customer Service Window** Randolph Building, Mail Stop Missing Parts 401 Dulany Street Alexandria, VA 22314

Sir:

The present communication is in response to the "NOTICE OF MISSING REQUIREMENTS UNDER 35 USC 371..." dated November 7, 2005. Attached hereto is/are:

- An executed oath or declaration in compliance with 37 C.F.R. 1.63, identifying the present application by title and priority information.
- [ ] An exact English language translation of the PCT application as originally filed.
  - [ ] Exact English language translation of the Annexes to the International Preliminary Examination Report containing substitute pages \_\_\_ of the specification and new claims \_\_\_\_ to be used for examination.
- A Preliminary Amendment [XX] Fees are reduced due to elimination of claim multiple dependencies. [XX]
- [XX] Copy of the "Sequence Listing" in computer readable form (CRF) and statement that contents of the CRF are the same as the paper copy.
- An Information Disclosure Statement with 08A- 1449 and references. 1
- [XX] Additional fees as calculated below:

			1 4
[XX] Search fee			\$400.00
[XX] Examination fee			\$200.00
Surcharge of \$130.00 for furnishing the oath or declaration later than [ ] 20 [XX] 30 months from the earliest claimed priority date (37 CFR 1.492(e)).			\$130.00
Number of each additional 50 pages or fraction thereof (round RATE			
up to a whole numbe	r)		
		X \$250.00	
Number of Claims	Number of Extra Claims	Rate	
Previously Paid For			}
53- 20 =	33	X \$ 50.00	\$1,650.00
5- 3 =	2	X \$200.00	\$400.00
Multiple Dependent Claims (if applicable)		+ \$360.00	\$
	TOTAL C	F ABOVE CALCULATIONS	\$2,780.00
Reduction of ½ for filing by small entity, if applicable. Applicant claims small entity status. See 37 CFR 1.27.			<\$ >
		SUBTOTAL	\$2,780.00
Processing fee of \$130.00 for late furnishing of the English translation.			\$
		TOTAL NATIONAL FEE	\$2,780.00

- Surcharge for late filing of the Declaration was paid on\_
- [XX] Total fees enclosed: \$ 2,780.00
- [XX] Credit Card Payment Form, PTO-2038, authorizing payment the amount of \$ 2,780.00 is enclosed to cover the above fees.
- [XX] Conditional Petition for Extension of Time:
  - If any extension of time for a response is required, applicant requests that this be considered a petition therefor.
- [XX] The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this application or credit any overpayment to Deposit Account No. 02-4035. This authorization and request is not limited to payment of all fees associated with this communication, including any Extension of Time fee, not covered by check or specific authorization, but is also intended to include all fees for the presentation of extra claims under 37 CFR 1.16 and all patent processing fees under 37 CFR 1.17 throughout the prosecution of the case. This blanket authorization does not include patent issue fees under 37 CFR 1.18.

By:

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400.00 GP 01 FC:1642 200.00 OP 02 FC:1633 03 FC:1617 04 FC:1615 130.00 DP 1650.00 OP 400.00 QP 05 FC:1614

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BROWDY AND NEIMARK, P Attorneys for Applicant(s)

lver P. Cooper

Registration No. 28,005

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit: In re Application of: ) Mogens FENGER ) Examiner: ) ) Appln. No.: 10/527,806 Washington, D.C. December 15, 2005 Filed: September 12, 2003 Docket No.: FENGER2 For: METHOD OF RAPID DETECTION) OF MUTATION AND NUCLEOTIDE Confirmation No.:3041 POLYMORPHISMS USING... )

## RESPONSE TO "SEQUENCE LISTING" REQUIREMENT

U.S. Patent and Trademark Office Customer Service Window Randolph Building, Mail Stop 401 Dulany Street Alexandria, VA 22314

#### Sir:

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In response to the Notice to Comply, mailed November 7, 2005:

- 1. Applicants hereby submit the following:
- [ ] a paper copy of a "Sequence Listing", complying with
   '1.821(c), to be incorporated into the specification
   as directed above;
- [ ] an amendment to the paper copy of the "Sequence Listing" submitted on , the amendment being in the form of substitute sheets;
- [XX] the Sequence Listing in computer readable form, complying with '1.821(e) and '1.824, including, if an amendment to the paper copy is submitted, all previously submitted data with the amendment incorporated therein;
- [ ] a substitute computer readable form to replace one found to be damaged or unreadable.
- [ ] The computer readable form in this application no. 09/... is identical with that filed on .... [date sequence was filed] in application no. 09/, filed

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[filing date]. In accordance with 37 C.F.R.
'1.821(e), please use the [first-filed, last-filed or only, whichever is applicable] computer readable form filed in that application as the computer readable form for the instant application. It is understood that the Patent and Trademark Office will make the necessary change in application number and filing date for the instant application. A paper copy of the Sequence Listing is [included in the originally-filed specification of the instant application, included in a separately filed preliminary amendment for incorporation into the specification, whichever is applicable].

- 2. The description is believed to be in compliance with '1.821(d).
- 3. The undersigned attorney or agent hereby states as follows:
  - (a) this submission does not include new matter
    ['1.821(g)];
  - (b) the contents of the paper copy (as amended, if applicable) and the computer readable form of the Sequence Listing, are the same ['1.821(f) and '1.825(b)];
  - (c) if the paper copy has been amended, the amendment is supported by the specification and does not include new matter ['1.825(a)]; and
  - (d) if the computer readable form submitted herewith is a substitute for a form found upon receipt by the PTO to be damaged or unreadable, that the substitute data is identical to that originally filed ['1.825(d)].

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4. Under U.S. rules, each sequence must be classified in <213> as an "Artificial Sequence", a sequence of "Unknown" origin, or a sequence originating in a particular organism, identified by its scientific name.

Neither the rules nor the MPEP clarify the nature of the relationship which must exist between a listed sequence and an organism for that organism to be identified as the origin of the sequence under <213>.

Hence, counsel may choose to identify a listed sequence as associated with a particular organism even though that sequence does not occur in nature by itself in that organism (it may be, e.g., an epitopic fragment of a naturally occurring protein, or a cDNA of a naturally occurring mRNA, or even a substitution mutant of a naturally occurring sequence). Hence, the identification of an organism in <213> should not be construed as an admission that the sequence per se occurs in nature in said organism.

Similarly, designation of a sequence as "artificial" should not be construed as a representation that the sequence has no association with any organism. For example, a primer or probe may be designated as "artificial" even though it is necessarily complementary to some target sequence, which may occur in nature. Or an "artificial" sequence may be a substitution mutant of a natural sequence, or a chimera of two or more natural sequences, or a cDNA (i.e., intron-free sequence) corresponding to an intron-containing gene, or otherwise a fragment of a natural sequence.

The Examiner should be able to judge the relationship of the enumerated sequences to natural sequences by giving full consideration to the specification, the art cited therein, any further art cited in an IDS, and the results of his or her sequence search against a database containing known natural sequences.

## USSN - 10/527,806 FENGER2

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C. Attorneys for Applicant(s)

By:

Aver P. Coop Registration No. 28,005

IPC:ses

624 Ninth Street, N.W. Washington, D.C. 20001

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### United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

U.S. APPLICATION NUMBER NO. FIRST NAMED APPLICANT ATTY, DOCKET NO. FENGER2 10/527,806 Mogens Fenger INTERNATIONAL APPLICATION NO. PCT/DK03/00594 1444 RECEIVED I.A. FILING DATE PRIORITY DATE BROWDY AND NEIMARK, P.L.L.C. 09/12/2003 09/13/2002 624 NINTH STREET, NW SUITE 300 2005 NOV - 9 **WASHINGTON, DG 20001-5303 CONFIRMATION NO. 3041 371 FORMALITIES LETTER** BROWDY AND NEIMARK WASHINGTON DIG 20094 \*OC000000017410644\*

Date Mailed: 11/07/2005

# MSP/SER/105 - 07 JA2006

# NOTIFICATION TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant is given **TWO MONTHS FROM THE DATE OF THIS NOTICE** within which to file the items indicated below to avoid abandonment. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

 Additional claim fees of \$6510 as a non-small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.

#### SUMMARY OF FEES DUE:

Total additional fees required for this application is \$7110 for a Large Entity:

- This application clearly fails to comply with the requirements of 37 CFR. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing", an initial paper or compact disc copy of the "Sequence Listing", as well as an amendment specifically directing its entry into the application. Applicant must also provide a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825 (d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821 (e) may be submitted in lieu of a new CRF.
- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice

published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.

- The application search fee has not been paid. Applicant must submit \$400 to complete the search fee. Note a surcharge will be required if submitted later than commencement of the national stage (37 CFR 1.492(h)) and the basic national fee was not paid before July 1, 2005.
- The application examination fee has not been paid. Applicant must submit \$200 to complete the examination fee for a non-small entity. Note a surcharge will be required if submitted later than commencement of the national stage (37 CFR 1.492(h)) and the basic national fee was not paid before July 1, 2005.
- Total additional claim fee(s) for this application is \$ 6510
  - \$200 for 1 independent claims over 3.
  - \$5950 for 119 total claims over 20.
  - \$360 for multiple dependent claim surchare.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- For Rules Interpretation, call (571) 272-0951
- For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.
- Send e-mail correspondence for Patentin Software Program Help @ ebc@uspto.gov

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

A copy of this notice **MUST** be returned with the response.

TAMALA D HOLLAND

Telephone: (703) 308-9140 EXT 209

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.

10/527,806 PCT/DK03/00594 FENGER2

FORM PCT/DO/EO/922 (371 Formalities Notice)